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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,216	02/20/2001	Mark Brian Anderson	0121-0005	3417
7590	07/03/2002			
Shanks & Herbert TransPotomac Plaza 1033 North Fairfax Street Suite 306 Alexandria, VA 22314			EXAMINER	
			LIU, HONG	
		ART UNIT	PAPER NUMBER	
		1624		

DATE MAILED: 07/03/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,216	Applicant(s) Anderson et al.
	Examiner Hong Liu	Art Unit 1624
<i>- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -</i>		
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status <p>1) <input type="checkbox"/> Responsive to communication(s) filed on _____</p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-8 and 10-16</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>10-16</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>1-8</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
Priority under 35 U.S.C. §§ 119 and 120 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). <p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
Attachment(s) <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>3</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>		

Art Unit: 1624

DETAILED ACTION

Claims 1-8 and 11-16 are pending in this application.

Election/Restriction

1. Applicant's election without traverse of Group I in Paper No. 6 is acknowledged.

In addition, applicants added new claims 13-16 which are generic claims of claims 1-8. A structure search of the claims revealed that there is prior art anticipating the newly added generic claims. The references include Mndzhoyan et al. (Khim. -Farm. Zh., 1988, 1986), US 3907700, and Mndzhoyan et al. (Arm. Khim. Zh. 1969), etc., which are provided in the Information Disclosure Statement. Because there is prior art for claims 13-16 but not for claim 1-8, it means that a technical feature which already forms part of the state of the art cannot, by definition, make a contribution over the prior art and does not, therefore, qualify as an unifying element in the sense of Rule 13.1 PCT. In other words, there is a lack of unity of invention between the groups of claims 1-8 and claims 13-16. For this reason, claims 13-16 are withdrawn from further consideration. Claims 11-12 are also withdrawn from consideration because they are with the same scope as that of the canceled claims 9 and 10. Applicants are expected to cancel the non-elected subject matter such that the claims will be commensurate to the scope of the elected subject matter in case it is found allowable.

Art Unit: 1624

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of "prodrug" is not adequately enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a "prodrug" will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

Art Unit: 1624

the invention. Claims 1-8 are vague and indefinite in that the metes and bounds of the "active metabolite" is unknown.

Information Disclosure Statement

Receipt is acknowledged of the Supplemental Information Disclosure Statement(s) later filed by applicants on December 5, 2001. However, copies of the references are not available to the examiner and therefore, the references are not considered. The references will be considered in due course if a copy is provided.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
June 30, 2002

Mukund J. Shah
Mukund Shah
Supervisory Patent Examiner
Art Unit 1624